









UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------------|----------------------|-------------------------|------------------|
| 09/888,272 | 06/21/2001 | Lone Wolinsky | 258/301 | 8637 |
| 23639 | 7590 01/27/2004 | | EXAMINER | |
| BINGHAM, MCCUTCHEN LLP THREE EMBARCADERO, SUITE 1800 | | | EVANISKO, GEORGE ROBERT | |
| | CISCO, CA 94111-4067 | 10 | ART UNIT | PAPER NUMBER |
| | • | | 3762 | |
| | | į | DATE MAILED: 01/27/2004 | (0 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
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| • | 09/888,272 | WOLINSKY ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | George R Evanisko | 3762 |
| The MAILING DATE of this communication appeared for Reply | ppears on the cover sheet with the | correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REP THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a re - If NO period for reply is specified above, the maximum statutory perio - Failure to reply within the set or extended period for reply will, by state - Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). Status | I. 1.136(a). In no event, however, may a reply be eply within the statutory minimum of thirty (30) d id will apply and will expire SIX (6) MONTHS fro ute, cause the application to become ABANDO | timely filed ays will be considered timely, on the mailing date of this communication, NED (35 U.S.C. § 133). |
| 1) Responsive to communication(s) filed on 10 | November 2003. | |
| 2a)⊠ This action is FINAL . 2b)□ Thi | is action is non-final. | |
| 3) Since this application is in condition for allow closed in accordance with the practice under | | |
| Disposition of Claims | | |
| 4) Claim(s) 61-103 is/are pending in the application 4a) Of the above claim(s) 99-103 is/are with 05. 5) Claim(s) is/are allowed. 6) Claim(s) 61-71,73-90 and 92-98 is/are reject 7) Claim(s) 72 and 91 is/are objected to. 8) Claim(s) are subject to restriction and | drawn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Examination The drawing(s) filed on is/are: a) and applicant may not request that any objection to the Replacement drawing sheet(s) including the correction. 11) The oath or declaration is objected to by the | ccepted or b) objected to by the one drawing(s) be held in abeyance. Section is required if the drawing(s) is a | See 37 CFR 1.85(a). objected to. See 37 CFR 1.121(d). |
| Priority under 35 U.S.C. §§ 119 and 120 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a li 13) Acknowledgment is made of a claim for dome since a specific reference was included in the 37 CFR 1.78. a) The translation of the foreign language priority acknowledgment is made of a claim for dome reference was included in the first sentence of | ents have been received. Ents have been received in Applicationity documents have been received in Applicationity documents have been received (PCT Rule 17.2(a)). St of the certified copies not receive stic priority under 35 U.S.C. § 119 first sentence of the specification provisional application has been restic priority under 35 U.S.C. §§ 12 | ation No ived in this National Stage ved. 9(e) (to a provisional application) or in an Application Data Sheet. eceived. 20 and/or 121 since a specific |
| Attachment(s) | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) Notice of Informa | rry (PTO-413) Paper No(s) I Patent Application (PTO-152) |

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DETAILED ACTION

Election/Restrictions

Newly submitted claims 99-103 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are a subcombination of the originally presented combination claims. The combination does not require the particulars of the subcombination as claimed, such as the energy storage device comprising a first relatively fast charging device and a second relatively slow charging device. The subcombination has separate utility by itself or in other combinations, not requiring the sensor or acoustic transducer and circuitry for transmitting an acoustic signal, but for powering a stimulation device.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 99-103 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 62-66, 77-79, 81-85, 87-89 and 96-98 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 62-66 and 81-85, "one or more acoustic transducers" is vague. It is unclear if these are the same transducers used in claims 61 and 80 or different/additional transducers.

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According to the arguments presented in the amendment and the way the independent claims read, the transducers both transmit and receive acoustic energy, but claims 62-66 and 81-85 have the transducers performing other functions such as "only" receiving or transmitting energy, operating in the full duplex mode (claim 62) and then operating by "only" receiving or transmitting (claim 63), or just operating in the half duplex mode (claim 65). The claims seem to conflict with the independent claims and each other.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 61-66, 71, 77, 80-85, 90, 92, and 96 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kovacs et al (5833603). Kovacs uses ultrasonic transducers (the claimed "acoustic" transducers) with a storage capacitor, 66 (the claimed energy storage device). In addition, Kovacs uses an integrated circuit controller which provides the claimed controller and circuitry.

In the alternative, Kovacs discloses the claimed invention with an IC control circuit to control the device and configure the transducers except for the control circuit and circuitry being separate elements. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable system as taught by Kovacs, with a separate control circuit and circuitry to control the device and configure the transducers since it was known in the art that implantable systems use separate control circuits and circuitry to perform

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different functions to allow the device to be easily assembled and provide circuitry with specific functions to reduce size and power requirements. In addition, it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61-66, 71, 73, 74, 77, 80-85, 90, 92, 93, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (6164284). Schulman discloses the use of ultrasonic transponders ("acoustic transducers") for receiving and transmitting data, such as pressure data, and discloses that the recharging of the battery can be done by other means (as seen in the incorporated Schulman et al reference, 6185452), but Schulman does not disclose that the one or more acoustic transducers are configured by the circuitry to also use

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acoustic/ultrasonic energy to convert acoustic energy into electrical energy (claims 61, 66, 80, and 85), and the one or more transducers are configured by the circuitry to operate in a full duplex, half duplex, or only transmit and only receive modes (claims 62-65 and 81-84). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the acoustic transducers as taught by Schulman, with one or more acoustic transducers configured by the circuitry to also convert acoustic energy into electrical energy or operate in a full duplex, half duplex, or only transmit and only receive modes since it was known in the art that acoustic transducers are configured by the circuitry to receive and transmit data and to receive acoustic energy to convert into electrical energy to provide one or more transducers in a compact configuration that perform all the functions so that multiple transducers and circuitry are not needed and since it was known in the art that acoustic transducers are configured by the circuitry to operate in a full duplex, half duplex, or only transmit and only receive mode, to allow the transducers and circuitry be easily configured to a particular application that does or doesn't require both receiving and transmitting functions. (Several examples of this can be seen in Kovacs et al, Doron et al, WO 99/34453, Feierback, 5861018, Ohara, 4041954, etc).

Claims 67-70 and 86-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman (or Kovacs) in view of Doron et al (WO 99/34453).

Schulman (or Kovacs) disclose the claimed invention except for the transducer having a substrate with a cavity and a substantially flexible piezoelectric layer across the cavity (claims 67 and 86), the transducer having a first external electrode and a second internal electrode (claims 68 and 87), the substrate comprising an array of cavities with the layer bonded to the substrate

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over the cavities (claims 69 and 88), and the layer being PVDF (claims 70 and 89). Doron teaches that it is known to use a transducer having a substrate with a cavity and a substantially flexible piezoelectric layer across the cavity, the transducer having a first external electrode and a second internal electrode, the substrate comprising an array of cavities with the layer bonded to the substrate over the cavities, and the layer being PVDF to provide a flexural piezoelectric transducer for converting and providing energy to a device and transmitting information from the device that is easily incorporated into the device, that is omnidirectional, that provides maximal response of the transducer while optimizing the electrode area, and to provide a larger energy collecting area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the acoustic medical device as taught by Schulman (or Kovacs), with the transducer having a substrate with a cavity and a substantially flexible piezoelectric layer across the cavity, the transducer having a first external electrode and a second internal electrode, the substrate comprising an array of cavities with the layer bonded to the substrate over the cavities, and the layer being PVDF as taught by Doron, since such a modification would provide an acoustic medical device with the transducer configured to be used as the acoustic transducer configured to convert energy for the power source and be used alternatively as an energy exchanger and transmitter having a substrate with a cavity and a substantially flexible piezoelectric layer across the cavity, the transducer having a first external electrode and a second internal electrode, the substrate comprising an array of cavities with the layer bonded to the substrate over the cavities, and the layer being PVDF to provide a flexural piezoelectric transducer for converting and providing energy to a device and transmitting information from the device that is easily incorporated into the device, that is omnidirectional, that provides maximal

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response of the transducer while optimizing the electrode area, and to provide a larger energy collecting area.

Claims 75, 76, 78, 79, 94, 95, 97, and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman (or Kovacs).

Schulman (or Kovacs) discloses the claimed invention except for the controller comprising reset circuitry for resetting the controller when the energy storage device is being charged (claims 75 and 94), automatically switching the implant off when the energy storage device falls below a predetermined threshold (claim 76 and 95), the controller extracting commands and controlling the implant by activating or deactivating the storage device based on the commands (claims 78 and 97), and monitoring when the energy conversion stops to activate the implant (claims 79 and 98). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Schulman (or Kovacs), with the controller comprising reset circuitry for resetting the controller when the energy storage device is being charged, automatically switching the implant off when the energy storage device falls below a predetermined threshold, the controller extracting commands and activating or deactivating the storage device based on the commands, and monitoring when the energy conversion stops to activate the implant since it was known in the art that IMD's use: the controller comprising reset circuitry for resetting the controller when the energy storage device is being charged to allow the device to not be corrupted by interference from the charging process and allow the controller to reboot to its original parameters if the energy was shutoff to the controller; automatically switching the implant off when the energy storage device falls below a predetermined threshold to prevent damaging the controller and energy storage device and/or to

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prevent bad data from being transmitted due to the low energy level; the controller extracting commands and controlling the implant from the energy converted and activating or deactivating the storage device based on the commands to quickly and efficiently transfer data while charging the device and to turn off the storage device when to not waste power; and monitoring when the energy conversion stops to activate the implant to prevent the charging process interfering with the implant and to allow the implant to fully charge before operations (i.e. sensing) is started to prevent corrupted data.

Allowable Subject Matter

Claims 72 and 91 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703 306-4520.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1148.

George R Evanisko Primary Examiner Art Unit 3762

GRE January 22, 2004